OCT 27 2010
K100027

510(k) Summary of Safety and Effectiveness

Date of Preparation: October 7, 2010

(a) (1) ***Submitted by:*** Solaris Medical Technology, Inc. (China)
6/F Building 9, 30th District, Keji Road,
Science Park, Nanshan District Shenzhen,
Guangdong, 518057 CHINA

Submitter Contact: Rachel Cheng
Vice President, Business Development
Solaris Medical Technology Inc. (USA)
Phone: +1 (650) 588-3980
Fax: +1 (650) 588-3988
rcheng@solarismedtech.com

(2) ***Trade Name:*** Solaris Medical Technology, Inc. Reusable & Disposable SpO_2 Sensors

Common Name: Pulse Oximeter Sensor

Classification Name: Oximeter

Classification Regulation: 21 CFR §870.2700

Product Code: DQA

Class: Class II

(3) ***Predicate Device(s):*** Substantial Equivalence to:

K Number	***Model***	***Manufacturer***
K993637*	Device Name MODEL 2500A Palmsat Pulse Oximeter (with model 8000AA Finger Clip Sensor, 7000A, 7000P, 7000I Flexi-Form II Disposable sensors specified)	Nellcor Puritan Bennett, Inc.

6/F Building 9, 30th District, Keji Road, Science Park, Nanshan District, Shenzhen Guangdong, 518057 CHINA
Tel: +86 755 26525478·Fax: +86 755 26525386·www.szsolaris.com

K Number	*Model*	*Manufacturer*
K050056*	Device Name MODEL 2500A Palmsat Pulse Oximeter (with model 8000AA Finger Clip Sensor, 7000A, 7000P, 7000I Flexi-Form II Disposable sensors specified)	Nonin Medical, Inc.
K000822*	Philips/Agilent component monitoring system, Agilent 24/26 (with model M1191A Reusable SpO2 Sensor specified as accessory)	Agilent Technologies, GmbH (formerly HP)
K042306	Philips M1131A SpO2 Disposable SpO2 Sensor	Philips Medizinsysteme Boeblingen GmbH (formerly HP)
K083705*	BCI WW1020 SPECTRO2 Pulse Oximeter (with model 3044 Reusable Finger Clip Sensor and model 1300 Disposable Finger Sensor, Adult specified as accessories)	Smiths Medical PM, Inc. (formerly SIMS BCI)

* Please note these 510(k) numbers represent monitors containing a pulse oximeter in which the predicate sensors were included as accessories.

Reason for Submission: New Device(s)

(4) ***Device Description:***

Solaris Compatible Reusable and Disposable SpO_2 Sensors (Solaris Sensors) are compatible sensors for use with major types of patient monitors and oximeter devices as listed above.

Solaris Sensors employ non-invasive electro-optical means to determine the light absorption of functional arterial hemoglobin. The sensor contains three optical components: two light emitting diodes (LED) that serve as light sources and one photodiode that acts as a light detector. The LED and photodiode are contained in the sensor housing.

Four types of sensor housings are described in this submission:

- Reusable soft finger sensor comprised of an integrated silicone rubber tube.
- Reusable finger clip sensor with rigid halves and silicone pads
- Disposable soft-digit sensor with flexible silicone housing
- Disposable adhesive sensors constructed of a medical tape laminate

6/F Building 9, 30th District, Keji Road, Science Park, Nanshan District, Shenzhen Guangdong, 518057 CHINA
Tel: +86 755 26525478·Fax: +86 755 26525386·www.szsolaris.com

Each sensor has unique labeling and specifications designed for compatibility with the specific monitor manufacturer (Nellcor, Nonin, HP/Philips, BCI).

(5) Intended use:

When used with a compatible patient monitor or a pulse oximeter device, Solaris Medical Technology, Inc. reusable & disposable SpO2 sensors are intended to be used for continuous, non-invasive functional arterial oxygen saturation (SpO2) and pulse rate monitoring.

Solaris Medical Technology, Inc. reusable multi-patient use SpO2 Soft Sensors, reusable multi-patient use SpO2 Finger Sensors, and disposable single patient use SpO2 Soft-finger Sensors are for use with adult/pediatric patients weighing greater than 40kg.

Solaris Medical Technology, Inc. disposable single patient use SpO2 Adhesive Sensors are for use with adult patients weighing greater than 40kg, pediatric patients weighing 10 – 40 kg, and infant (non-neonatal) patients weighing 3 – 15 kg.

Prescription device.

(6) ***Technology Comparison:***

Solaris Sensors employ the same technological characteristics as the predicate devices to determine arterial oxygen saturation: arterially perfused tissue is illuminated sequentially by two wavelengths of LEDs, and the time varying absorbance of the tissue is measured by a photodetector.

This method is characteristic of all sensors that are the subject of this submission as well as the predicate devices.

(b) (1) ***Non-Clinical Performance Tests:***

Cleaning Instruction Testing
Solaris Sensors were tested in accordance with internal protocols to ensure that the cleaning instructions do not damage sensor labeling or degrade the material.

6/F Building 9, 30th District, Keji Road, Science Park, Nanshan District, Shenzhen Guangdong, 518057 CHINA
Tel: +86 755 26525478·Fax: +86 755 26525386·www.szsolaris.com

Biocompatibility
Sensor patient contact materials meet applicable standards for biocompatibility.

Electrical Safety and EMC Testing
The sensors were tested in accordance with current applicable standards for medical device Electrical Safety and Electromagnetic Compatibility. Test results indicated that the sensors comply with the stated clauses.

Pulse Rate Accuracy Testing
The sensors were tested for pulse rate accuracy with a listed SpO2 simulator with predicate device monitors. The sensors met their specified pulse accuracy.

(2) ***Clinical Testing:***

Solaris Sensors were clinically tested to validate the performance and accuracy of the Solaris Reusable and Disposable sensors under controlled hypoxia versus arterial oxygen saturation as determined by co-oximetry. All testing was performed under an institutionally approved protocol with subject informed consent.

Clinical test results indicated that the sensors meet the stated accuracy claims over the 70 % - 100 % range.

(3) ***Conclusions:***

Based upon device evaluations, predicate comparisons, and performance testing results, Solaris Reusable and Disposable SpO_2 Sensors are substantially equivalent to the predicate devices.

6/F Building 9, 30th District, Keji Road, Science Park, Nanshan District, Shenzhen Guangdong, 518057 CHINA
Tel: +86 755 26525478 Fax: +86 755 26525386 www.szsolaris.com

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Rachel Cheng
Vice President, Business Development
Solaris Medical Technology, Incorporated
400 Oyster Point Boulevard, Suite 534
South San Francisco, California 94080

OCT 7 2010

Re: K100077
Trade/Device Name: Solaris Reusable & Disposable SpO_2 Sensors
Regulation Number: 21 CFR 870.2700
Regulation Name: Accessory to Pulse Oximeter
Regulatory Class: II
Product Code: DQA
Dated: October 2, 2010
Received: October 4, 2010

Dear Ms. Cheng:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Solaris Medical Technology, Inc. Reusable & Disposable SpO_2 Sensors

Indications for use:

When used with a compatible patient monitor or a pulse oximeter device, Solaris Medical Technology, Inc. reusable & disposable SpO_2 sensors are intended to be used for continuous, non-invasive functional arterial oxygen saturation (SpO_2) and pulse rate monitoring.

Solaris Medical Technology, Inc. reusable multi-patient use SpO_2 Soft Sensors, reusable multi-patient use SpO_2 Finger Sensors, and disposable single patient use SpO_2 Soft-finger Sensors are for use with adult/pediatric patients weighing greater than 40kg.

Solaris Medical Technology, Inc. disposable single patient use SpO_2 Adhesive Sensors are for use with adult patients weighing greater than 40kg, pediatric patients weighing 10 – 40 kg, and infant (non-neonatal) patients weighing 3 – 15 kg.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

Prescription Use ___X___ AND / OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: k/0007